

Message Text

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ORIGIN HEW-06

INFO OCT-01 AF-10 ARA-14 EUR-12 EA-12 NEA-10 ISO-00
OES-07 MED-03 SIG-02 /077 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CM
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/PHS/OASH/OIH: RBUHRICH, M.D.
EUR/EX:JSHINN(INFO)
EA/EX:JBMORAN(INFO)
NEA/EX:JSCONNOLLY(INFO)
EUR/EX:DCLEIDEL(INFO)
ARA/EX:GAPAGANO(INFO)
AF/EX:EGKRYZA(INFO)

-----010086 010247Z /64

P 312159Z AUG 77
FM SECSTATE WASHDC
TO AMEMBASSY NEW DELHI PRIORITY
AMEMBASSY WELLINGTON PRIORITY
AMEMBASSY CANBERRA PRIORITY
AMEMBASSY SINGAPORE PRIORITY
AMEMBASSY PANAMA PRIORITY
AMEMBASSY BEIRUT PRIORITY
AMEMBASSY PRETORIA PRIORITY
AMEMBASSY LONDON PRIORITY
AMEMBASSY MEXICO PRIORITY
AMEMBASSY PARIS PRIORITY
AMEMBASSY LAGOS PRIORITY
AMEMBASSY BONN PRIORITY
AMEMBASSY THE HAGUE PRIORITY

UNCLAS STATE 208814

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, IN, NZ, SN, PN, LE,

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SUBJECT: POTENTIAL ELECTRONICHAZARD IN PATIENT MONIT-
ORING SYSTEMS (RECALL T/089-7 TO T-097-7)
TAGS (CONT'D) SF, UK, MX, FR, NI, GW, NL

1. FDA ADVISES OF THE FOLLOWING:

A. RECALL T-089-7 - ECG MODULES, MODELS SM 1035, SM 1054,

SM 1055, SM 1065, SM 1066, SM 1081, AND SM 7066.

B. RECALL T-090-7 - ECG AMPLIFIER AND FIVE INCH SCOPE,
MODELS SM 1041 THROUGH 1044.

C. RECALL T-091-7 - ECG/APNEA MONITOR, MODELS SM 1057
AND SM 7057.

D. RECALL T-092-7 - CABINETS, MODELS SM 1015, SM 1022,
SM 1027, SM 1076, SM 1078, SM 1079, SM 1087, SM 1068,
SM 1069, SM 1051, SM 1053, SM 1020, SM 1061

E. RECALL T-093-7 - EEG AMPLIFIER MODULE, MODEL SM
1062

F. RECALL T-094-7 - RESPIRATION MODULE MODELS SM 1010
AND SM 7010

G. RECALL T-095-7 - BED JUNCTION BOXES OR PANELS;
SEVEN CHANNEL MODELS SM 4014, 4314, 4328; FOUR CHANNEL
MODELS SM 4016, 4017, 4316, 4327; TWO CHANNEL MODELS
SM 4015, 4315, 4317, 4329

H. RECALL T-096-7 - TWO LEAD RESPIRATION MONITORING
CABLE MODELS SM 5124 AND SM 5026.

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I. RECALL T-097-7 - THREE LEAD EEG PATIENT CABLES,
MODELS SM 5129 AND SM 5029.

PRODUCTS INVOLVED: 45 DIFFERENT MODELS OF GOULD
STATHAM PATIENT MONITORING SYSTEMS. THESE INCLUDE
ECG MODULES, EEG MODULES, RESPIRATION MODULES,
CABINETS, AND CABLE CONNECTORS.

PRODUCT IDENTIFICATION: REFER TO THE FOLLOWING LISTS
OF MODEL NUMBERS. NOTE THAT ALL SUFFIX LETTERS WHICH
MAY APPEAR AT THE END OF THE MODEL NUMBER ARE ALSO
INCLUDED IN THE RECALL. THE MODEL NUMBERS WHICH ARE
PRECEDED BY AN X INDICATE THAT CERTAIN SERIAL NUMBERS
HAVE ALREADY INCORPORATED THE KEYING MODIFICATIONS.
ONLY THE SERIAL NUMBERS OF THE X MODEL NUMBERS HAVE HAD
THE REQUIRED MODIFICATION.

FOR ALL 45 MODEL NUMBERS, ALL SERIAL NUMBERS (EXCEPT
THOSE SPECIFICALLY LISTED AS HAVING BEEN MODIFIED) ARE
INVOLVED IN RECALL.

COMPONENTS OF THE FOLLOWING 45 GOULD STATHAM PATIENT

MONITORING SYSTEMS ARE INVOLVED IN RECALL:

ECG MODULES (RECALL T-089-7)

ECG MODULES (RECALL T-089-7)

MODELS: SM1035

SM1054

SM1055

SM1065

XSM1066

SM1081

XSM7066

ECG AMPLIFIER & 5" SCOPE (RECALL T-090-7)

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MODELS: SM1041

SM1042

XSM1043

SM1044

ECG/APNEA MONITOR (RECALL T-091-7)

MODELS: SM1057

SM7057

CABINETS (RECALL T-092-7)

MODELS: XSM1015

SM1022

SM1037

XSM1076

SM1078

SM1079

XSM1087

XSM1068

SM1069

XSM1052

SM1053

SM1020

XSM1061

AMPLIFIER MODULE (RECALL T-093-7)

MODEL: SM1062

RESPIRATION MODULE (RECALL T-094-7)

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MODELS: SM1010
SM7010

BED JUNCTION BOXES OR PANELS (RECALL T-095-7)

SEVEN CHANNEL MODELS:

SM4014
SM4314
SM4328
SM4330

FOUR CHANNEL MODELS: TWO CHANNEL MODELS:

SM4016	SM4015
SM4017	SM4315
SM4316	SM4317
SM4327	SM4329

TWO LEAD RESPIRATION MONITORING CABLE (RECALL
T-096-7)

MODELS: SM5124
SM5026

THREE LEAD EEG PATIENT CABLE (RECALL T-097-7)

MODELS: SM5124
SM5029

THE FOLLOWING LIST OF 9 DIFFERENT MODELS SPECIFIES
THE SPECIFIC SERIAL NUMBERS WHICH HAVE HAD THE MODI-
FICATIONS AS REQUIRED. THESE SERIAL NUMBERS ARE NOT
INVOLVED IN RECALL.

MODEL NUMBER	MODEL NUMBER
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SM101015 CABINET SM1076 CABINET

S/N 2104	S/N 450	1984
2105	1878	1985
2106	1886	1986
2107	1951	1987
2108	1958	1988

2112 1960 1989
2118 1961 1992 & SUBSEQUENT
2119 1973
2121 & SUBSEQUENT 1974
1976
1977
1978
MODEL NUMBER 1979
SM1061 1980
S/N 301 1981
457 1982
459 & SUBSEQUENT 1983

MODEL NUMBER
SM1087 CABINET
S/N 425 & SUBSEQUENT

MODEL NUMBER MODEL NUMBER
SM7066 ECG MODULE SM1052 SURGERY
(DIGITAL DISPLAY) MONITOR

S/N 1223 S/N 765 & SUBSEQUENT
1224
1226
1227
1229 & SUBSEQUENT MODEL NUMBER
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MODEL NUMBER S/N 744
SM1066 ECG MODULE 752 & SUBSEQUENT
(ANALOGUE DISPLAY)
S/N 1013
1219
1228 MODEL NUMBER
1230 SM1043 COMBINED HEART
1231 MONITOR MODULE
1232 S/N 352
1233 354
1235 & SUBSEQUENT 60I & SUBSEQUENT

MANUFACTURER/RECALLING FIRM: GOULD, INC., MEASUREMENT
SYSTEMS DIVISION, 2230 STATHAM BLVD., OXNARD,
CALIFORNIA 93030

2. REASON FOR RECALL: THERE IS A POTENTIAL FOR THE
PATIENT TO RECEIVE SKIN TINGLING SHOCKS AND SKIN BURNS
IF THE PRODUCTS ARE MISCONNECTED. CARDIAC ARRHYTHMIA
CAN OCCUR IN THOSE PATIENTS WHO ARE ELECTRICALLY
SUSCEPTIBLE, I.E., THOSE PATIENTS WITH INDWELLING

CARDIAC CATHETERS.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY ARE AWARE OF RECALL AND HAVE RECEIVED COMMUNICATION FROM FIRM DATED 12 NOVEMBER 1976 REGARDING PROBLEMS AND MODIFICATIONS REQUIRED TO PREVENT POSSIBLE USE ERROR AND PATIENT INJURY. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING RECALL SHOULD BE DIRECTED TO FIRM.

4. FOREIGN CONSIGNEES AS FOLLOWS:

INDIA, SURGEON TO THE PRESIDENT OF
PRESIDENTS DISPENSARY
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GOVERNMENT HOUSE
NEW DELHI 4
INDIA

C. LACKLAND & CO., LTD.
P. O. BOX 56-036
27-329 DOMINION ROAD
AUCKLAND 3
NEW ZEALAND

MEDOS COMPANY, LTD.
P. O. BOX 192
PORT MELBOURNE 3207
AUSTRALIA

I. PARRISH PTY. LTD.
37D/2970 THIRD FLOOR
ELEGIE COMPLEX
ELEGIE ROAD
SINGAPORE 7

PROMED S.A.
P. O. BOX 6281
PANAMA 5
REPUBLIC OF PANAMA

RICHARD DUMBAKLY & CO.
MAR MAMSOUR ST., P. O. BOX 1710
BANK BEIRUT & ARAB COUNTRIES BLDG.
BEIRUT
LEBANON

PROCESS CONTROL INSTRUMENTATION
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PTY LTD.
P. O. BOX 5912
JOHANNESBURG
SOUTH AFRICA

P. K. MORGAN LTD.
10 MANOR ROAD
CHATHAM KENT ENGLAND

POCHTECA INTERNATIONAL S.A.
DR. LUCIO 103-7
MEXICO 7 D.F.
MEXICO

INST SEGURIOAD, SERVICIOS SOCIALES
DE LOS TRABAJADORES DEL ESTADO
AVE. SAN FERNANDO, 547, 200 PISO
ILALPAN 22
MEXICO, DF, MEXICO

HORACIO ICAZA Y CIA., S.A.
LA CASA DEL MEDICO
APDO. 2689
PANAMA 1, REPUBLICA DE PANAMA

ETS DELHOMME & CIE
30, BOUL. ST-JACQUES
PARIS 14
FRANCE

PAN AFRICA INVEST LTD.
284 HERBERT MACAULEY ST. YABA
G. P. O. BOX 1474
LAGOS,
NIGERIA

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W. A. SHUBART
DIPL. PHYSIKER GUNTHER
33 HAGENAUER STREET
D6202 WIESBADEN
WEST GERMANY

GOULD-GODART

JAN VAN EYCKLAAN 2
BILTHOVEN, HOLLAND CHRISTOPHER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 31-Aug-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE208814
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CM
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770315-1154
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t1977081/aaaaaawu.tel
Line Count: 388
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: f055fb4d-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 8
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 15-Nov-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 1395550
Secure: OPEN
Status: NATIVE
Subject: POTENTIAL ELECTRONICHAZARD IN PATIENT MONITORING SYSTEMS (RECALL T/089-7 TO T-097-7) TAGS (CONT'D) SF, UK, MX, FR, NI, GW, NL
TAGS: OGEN, ETRD, EIND, TBIO, IN, NZ, SN, PN, LE
To: NEW DELHI WELLINGTON MULTIPLE
Type: TE
vdkgvwkey: odbc://SAS/SAS.dbo.SAS_Docs/f055fb4d-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
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